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FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. APPLICATION NO. FILING DATE 5506 43662-Amedica 10/737,108 12/15/2003 Ashok C. Khandkar EXAMINER 7590 08/23/2004 BLANCO, JAVIER G KELLY BAUERSFELD LOWRY & KELLEY, LLP Stuart O. Lowry ART UNIT PAPER NUMBER Suite 1650 6320 Canoga Avenue 3738

DATE MAILED: 08/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<u> </u>	Application No.	Applicant(s)	P
	10/737,108	KHANDKAR ET AL.	(
Office Action Summary	Examiner	Art Unit	
	Javier G. Blanco	3738	
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply			
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).			
Status			
1) Responsive to communication(s) filed on <u>01 June 2004</u> .			
2a) ☐ This action is FINAL . 2b) ☑ This	action is non-final.		
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.			
Disposition of Claims			
4) ☐ Claim(s) 1-53 is/are pending in the application. 4a) Of the above claim(s) 4-6 and 17-41 is/are withdrawn from consideration. 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 1-3,7-16 and 42-53 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/or election requirement.			
Application Papers			
9) The specification is objected to by the Examiner.			
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.			
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).			
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.			
Priority under 35 U.S.C. § 119			
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 			
Attachment(s)			
Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948)	4) Interview Summary Paper No(s)/Mail D		
 Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>5/13/2004</u>. 		Patent Application (PTO-152))

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DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Total Disc Implant: Species C (Figures 16-21) in the reply filed on June 1st, 2004 is acknowledged.

2. Claims 4-6 and 17-41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on June 1st, 2004.

Claim Objections

- 3. Claims 9, 16, 42, 44, and 53 are objected to because of the following informalities:
- a. Regarding claim 9, please delete "one of said" (see line 2). Appropriate correction is required.
- **b.** Regarding claim 16, please add --bearing-- after "cylindrical" (see line 2). Appropriate correction is required.
- c. Regarding claim 42, please substitute "bearing strip" (see line 4) with --, generally part-cylindrical bearing surfaces-- (as in claim 1). Appropriate correction is required.
- **d.** Regarding claim 44, please delete "one of said" (see line 2). Appropriate correction is required.
- e. Regarding claim 53, please add --bearing-- after "cylindrical" (see line 2). Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 5. Claims 1-3, 7-16, and 42-53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- a. Regarding claim 1, a "part-cylindrical bearing surface" (see lines 4-5) is vague and confusing, rendering the claim indefinite. None of Figures 1-21 shows a bearing surface or strip having a "part-cylindrical" configuration. As shown in Figure 16 (as part of the elected species), each of the opposite ends of a bearing surface or strip is convex and flares out. The bearing seat is generally concave and its sides (from a top view) are also concave. Claims 2, 3, and 7-16 depend on claim 1.
- b. Regarding claims 3, 8, and 43, a "generally flattened base" is vague and confusing, rendering the claim indefinite. None of Figures 1-21 shows a bearing surface or strip having a "generally flattened base" configuration. As shown in Figure 16 (as part of the elected species), the bearing seat is generally concave and its sides (from a top view) are also concave.
- c. Regarding claim 9, "the associated concave central segment" (see lines 3-4) lacks antecedent basis.
- d. Regarding claim 42, a "part-cylindrical bearing surface" (see line 6) is vague and confusing, rendering the claim indefinite. None of Figures 1-21 shows a bearing surface or strip having a "part-cylindrical" configuration. As shown in Figure 16 (as part of the elected species), each of the opposite ends of a bearing surface or strip is convex and flares out. The bearing seat is generally concave and its sides (from a top view) are also concave. Claims 43-53 depend on claim 42.

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e. Regarding claim 44, "the associated concave central segment" (see lines 3-4) lacks antecedent basis.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 7. Claims 1-3, 7-15, and 42-51 are rejected, <u>as best understood</u>, under 35 U.S.C. 102(b) as being clearly anticipated by Buettner-Janz et al. (US 4,759,766 A).

As seen in Figures 1-25, Buettner-Janz et al. discloses a disc implant comprising a pair of end plates (end plates 11) and a pair of bearing components formed respectively on said end plates and respectively defining a pair of elongated part-cylindrical bearing surfaces (disclosed as "partial surfaces of a cylinder") extending generally on orthogonal axes relative to each other (see Figures 10A, 12, and 17; Abstract; column 2, line 67 to column 3, line 4; column 5, lines 50-56). A bearing seat (spacing piece 12) is also provided. Said bearing seat presents either a convex center portion (Figure 2) or a concave center portion (Figure 10A). The center portions of the end plates could be either concave or convex (Figure 10A). Additionally, a pin (another example of a "part-cylindrical bearing surface") could be provided at the center portion of the end plates, and a matching/corresponding recess provided at the center portion of the spacing piece (see column 3, lines 20-26; column 6, lines 5-10 and lines 14-17). The end plates are made of metal

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and are provided with teeth as an anchoring mechanism. The end plates could also be provided with a bioactive coating (see column 2, lines 61-64).

Claim Rejections - 35 USC § 103

- 8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 9. Claims 16, 52, and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buettner-Janz et al. (US 4,759,766 A).

Buettner-Janz et al. disclose the invention as claimed (see 102(b) rejection above) except for particularly disclosing the use of a ceramic material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have used a ceramic material as part of Buettner-Janz et al. invention, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Erickson et al. (US 6,368,350 B1), Krueger et al. (US 2004/0143332), Marino et al. (WO 99/60956), Baumgartner et al. (WO 2004/019828), Baumgartner et al. (WO 2004/026186), and Frigg et al. (WO 2004/054479).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 703-605-4259. The examiner can normally be reached on M-F (7:30 a.m.-4:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications and After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

JGB

August 13, 2004

David H. Willse Primary Examiner